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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/047,745	01/15/2002	James M. Campos	ROWE/03	5179
26875	7590	10/19/2004	EXAMINER	
WOOD, HERRON & EVANS, LLP 2700 CAREW TOWER 441 VINE STREET CINCINNATI, OH 45202			SCHAETZLE, KENNEDY	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/047,745

Applicant(s)

CAMPOS, JAMES M.

Examiner

Kennedy Schaetzle

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) 29 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-27, 31-56, 58 and 59 is/are allowed.
- 6) ☒ Claim(s) 28, 30 and 57 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 January 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 4/19/02.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of the species covered by claims 1-3, 6-9, 11, 14, 15, 17, 19, 20, 22-28, 30, 33, 35-39, 41-43, 45 and 47-59 in the reply filed on July 21, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. The examiner notes that the above listing provided by the applicant did not include claim 31. Since claim 31 was considered to be generic, the applicant is entitled to examination of this claim as well.
3. It is further noted that the above listings inclusion of claim 37 appears to be in error since this claim is directed to a non-elected species. The examiner will consider this claim withdrawn from consideration, but requests confirmation by the applicant.

### ***Drawings***

4. Figures 12A-C should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.121(d)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Objections***

5. Claim 58 is objected to because of the following informalities: the recitation "...sequence of pulses the musculature via the electrodes..." (line 6) is grammatically awkward. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 2, 3, 6-8, 11, 14, 15, 19, 22-27, 31, 33, 35, 36, 38, 41-43, 47 and 49-56 rejected under 35 U.S.C. 102(b) as being anticipated by Kallok (Pat. No. 5,133,354).

Regarding claim 1 and claims with similar limitations, Kallok discloses a method of stimulating musculature comprising applying a resonant sequence of pulses (see Figs. 3 and 4, for example), spaced relative to one another such that each pulse subsequent to a first pulse in the sequence is effective to progressively stimulate and create tension in the musculature inwardly from the electrodes and towards the center of the musculature while maintaining the tension created in at least a portion of the musculature by each preceding pulse in the resonant sequence (note Fig. 1a-c and the text abridging cols. 2 and 3 wherein tension is cumulatively increased with each stimulation pulse). The examiner considers it inherent that the tension is created inwardly from the electrodes to the center of the musculature because stimulation resulting from the application of energy from an electrode naturally propagates outwardly from the source of stimulation such as shown in prior art Figs. 12A-C, with the difference between said prior art figures and the Kallok reference being that tension is maintained in the musculature with the Kallok pulsing system.

Regarding claims 2 and 3, since the applicant has not set forth the definition of a resonant sequence explicitly and with reasonable clarity, deliberateness and precision, one can arbitrarily consider pulse 80 (see Fig. 3) to be a first pulse and pulse 82 to be a second pulse of a resonant sequence. The first pulse has a frequency or spacing different from the second pulse.

Regarding claims 6 and 27, Kallok discloses the use of multiple sequences (note for example Fig. 4).

Regarding claims 7 and 8, a first sequence 98 has a different parameter than a second sequence 100 (note Fig. 4).

Regarding claim 11, the square wave pulse sequences shown in Fig. 4 are considered out of phase because they do not occur simultaneously.

Regarding claim 14, any system designed and manufactured to produce a certain polarity of pulse can be said to have polarities determined according to a "polar profile." The "polar profile" can simply relate to a pulse design criteria established by the profiler (i.e., circuit designer) prior to construction of the invention.

Regarding claim 15, Kallok has selected a sequence of four pulses.

Regarding claims 22 and 23, Kallok teaches that the frequency (i.e., pulse rate) of output pulses may be adjusted either manually or automatically (note col. 2, lines 13-24). A user interface would inherently be required to allow for such adjustment.

Regarding claim 24, an implantable unit is inherently configured for attachment to a user.

Regarding claim 25, whether the user interface fits within a pocket of the wearer simply depends upon how big the pocket is. The pocket is a non-element of the invention. The examiner considers any implantable device (and even more so a subunit of the device such as a user interface which may simply relate to a telemetry coil or a set of sensing electrodes, etc.) to be configured for fitting within a pocket.

Regarding claim 26, since the applicant has chosen not to invoke the 6<sup>th</sup> paragraph of §112, the examiner is free to interpret the term "user interface" and "diagnostic equipment" in its broadest reasonable sense and is not limited to embodiments disclosed by the applicant and equivalents thereof. In this case, the examiner considers the user interface to be the sensing electrodes that interface to the body and enable the frequency of output pulses to be automatically adjusted. The electrodes are considered to be diagnostic equipment. Other interpretations are possible due to the broadness of the claim.

Comments related to those above apply to substantially similar apparatus claims 31, 33, 35, 36, 38, 41-43, 47 and 49-56.

8. Claims 28, 30 and 57 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Hagfors et al. (Pat. No. 3,911,930).

See Fig. 3 wherein the first pulse designation is assigned to the pulse of shortest width, and the second pulse designation is assigned to the 500 microsecond pulse.

It should be noted that in the examiner's opinion, the above claim set is extremely broad in scope, and thus, numerous references would appear to read on the listed claims. In the interests of compact prosecution, it is highly recommended that the applicant either cancel claims of this scope, or substantially amend to avoid Final rejection on second action.

#### ***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 9, 20, 39, 48, 58 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kallok.

Regarding claims 9 and 39, Kallok does not disclose the recited pulse spacing of 3-10 microseconds. Since both the intent of the applicant and Kallok is to space the pulses to maintain tension in the musculature, it would have been obvious to employ any spacing suitable to achieve this goal. Those of ordinary skill in the art would have further considered the exact spacing to be dependent upon the type of muscle being stimulated, pulse energy and the condition of the patient under treatment.

Concerning claims 20 and 48, Kallok does not disclose generating a sequence wherein successive pulses have a shorter width than preceding pulses. The phenomena of muscle fatigue is, however, widely known by those of ordinary skill in the art, along with stimulation techniques to combat such fatigue. The examiner takes Official Notice that it is old and well-known to reduce muscle adaptation resultant from

stimulation by modifying parameters of the stimulation pulse such as width, frequency, amplitude, etc. To alter the pulse width from one pulse to the next so as to provide a varied signal would have been considered a matter of obvious design by those of ordinary skill in the stimulator arts.

With respect to claims 58 and 59, while Kallok does not explicitly refer to the use of a program product, the examiner does not consider the product to be patentably distinct from the method and apparatus as evidenced by the restriction requirement grouping the three inventions together. In any event, those of ordinary skill in the electronics arts would have seen the provision of a memory device containing programming code to control operation of the implantable medical device set forth by Kallok to be a matter of obvious design. Official Notice is taken that the use of programs stored on recordable and "transmission-type" media to control medical devices is old and well-known in the art.

11. Claims 17 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kallok in view of Schulman et al. (Pat. No. 5,193,539).

Regarding claims 17 and 45, Kallok does not recite the use of charge-balanced pulses. Schulman et al., however, teach that charge-balanced pulses help to prevent damage to body tissues from constant application of currents in one direction. Given that the use of such pulses are old and well-known in the medical stimulator arts, and given the universal teaching that damage can be prevented in body tissues by using such pulses, those of ordinary skill in the art desiring to prevent muscle damage would have seen the obviousness of employing charge-balanced pulses in the system of Kallok.

### ***Conclusion***

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Art Unit: 3762

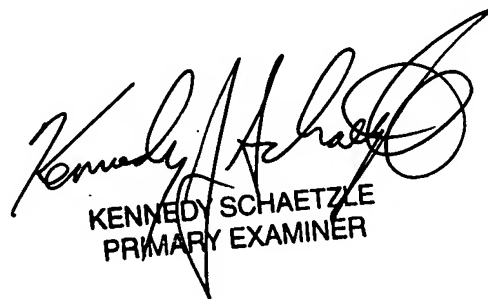
13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 703 308-2211. The examiner can normally be reached on M-W, F from 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-0851. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KJS

October 14, 2004



KENNEDY SCHAETZLE  
PRIMARY EXAMINER